

AMENDED IN SENATE JUNE 2, 2003

AMENDED IN SENATE MAY 23, 2003

AMENDED IN SENATE MAY 8, 2003

AMENDED IN SENATE APRIL 24, 2003

AMENDED IN SENATE APRIL 21, 2003

SENATE BILL**No. 506**

Introduced by Senator Sher

February 20, 2003

An act to amend Section 4164 of the Business and Professions Code, *and to amend Sections 14328 and 15051 of the Food and Agricultural Code*, relating to pharmaceuticals, *and making an appropriation therefor*.

LEGISLATIVE COUNSEL'S DIGEST

SB 506, as amended, Sher. Pharmaceuticals: wholesalers and manufacturers' reporting requirements.

The Pharmacy Law, administered by the California State Board of Pharmacy in the Department of Consumer Affairs, makes it unlawful for any person other than a pharmacist to compound or dispense a dangerous drug or device, or to compound or dispense a prescription. Existing law provides exemptions from this prohibition for specified persons. A knowing violation of the Pharmacy Law is a crime.

Existing law requires wholesalers licensed by the board and manufacturers who distribute controlled substances, dangerous drugs, or dangerous devices within or into the state to report to the board all

sales of dangerous drugs and controlled substances that are subject to abuse.

This bill would also require ~~these~~ *wholesalers licensed by the board and manufacturers who directly distribute dangerous drugs or dangerous devices to retailers within the state* to report to the board specified information on all sales of antibiotics *for use on livestock, poultry, or other food producing animals*. The bill would require the board, beginning on January 1, 2006, to compile annually the information and to provide on its Web site notice of its availability. The bill would require the board to aggregate data where possible if disclosure would reveal legitimate confidential business information of an individual company. The bill would authorize the board to impose fees on wholesalers and manufacturers subject to these provisions and would prohibit the fees from exceeding its costs in implementing the provisions.

Existing law prohibits a person without a license from the Department of Food and Agriculture from selling a restricted livestock drug in this state at retail, and requires a licensee to keep a record of his or her sales of restricted drugs. Existing law requires a person, except as specified, to obtain a license from the Secretary of the Department of Food and Agriculture (1) for each location where commercial feed is manufactured, distributed, sold, or stored for sale, (2) if the person does not have a permanent place of business but manufactures, distributes, sells, or stores feed, or (3) if the person's name and address appear on the label of commercial feed as guarantor. A violation of these provisions is a crime.

This bill would require these licensees to report to the department sales of oral and injectable antibiotics or feed that contains antibiotics, as specified. The bill would authorize the department to impose fees on those persons, not to exceed the cost of collecting, collating, and disseminating the information.

Because the fees authorized by this bill would be deposited into the continuously appropriated Food and Agriculture Fund, the increase would result in an appropriation.

Because violations of this bill would be a misdemeanor, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: ~~no~~—yes. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

- 1 SECTION 1. Section 4164 of the Business and Professions
2 Code is amended to read:
- 3 4164. (a) All wholesalers licensed by the board and all
4 manufacturers who distribute controlled substances, dangerous
5 drugs, or dangerous devices within or into this state shall report to
6 the board all sales of dangerous drugs and controlled substances
7 that are subject to abuse, as determined by the board.
- 8 (b) Notwithstanding subdivision (a), all wholesalers licensed
9 by the board and all manufacturers who *directly* distribute
10 dangerous drugs or dangerous devices *to retailers* within this state
11 shall report to the board all sales of antibiotics *for use on livestock,*
12 *poultry, or other food-producing animals,* in a time and manner
13 chosen by the board. The report shall include, but is not limited to,
14 all of the following:
- 15 (1) The identity of the antibiotic, including its generic and trade
16 name.
- 17 (2) The market status of the antibiotic.
- 18 (3) The claimed use and targeted use of the antibiotic.
- 19 (4) Any other information the board deems appropriate.
- 20 (c) Beginning on January 1, 2006, and annually thereafter, the
21 board shall compile this information, and provide notice on its
22 Web site that the information is available.
- 23 (d) If disclosure, as required in subdivision (b), of antibiotic
24 sales data for an individual company would reveal legitimate
25 confidential business information, the board shall aggregate the
26 data where possible to avoid disclosure of that confidential
27 business information. Any personal identifying information
28 accompanying the antibiotic sales data shall remain confidential.
- 29 (e) The board may impose fees on wholesalers and
30 manufacturers subject to this section. The fees may not exceed the
31 amount of the board's costs of collecting, collating, and
32 disseminating information pursuant to this section.

1 SEC. 2. *Section 14328 of the Food and Agricultural Code is*
2 *amended to read:*

3 14328. (a) Each holder of a license under this chapter shall
4 keep a record, in the manner and form prescribed by the director,
5 of each sale of a restricted drug by the licensee.

6 (b) *Notwithstanding subdivision (a), each holder of a license*
7 *under this chapter shall report to the department, on a form*
8 *prescribed by the department, all sales of oral and injectable*
9 *antibiotics. The form shall include, but is not limited to, all of the*
10 *following information:*

11 (1) *The NADA code and identity of the antibiotic, including its*
12 *generic and trade name.*

13 (2) *The market status of the antibiotic.*

14 (3) *The dosage and form of the antibiotic.*

15 (4) *The claimed use, targeted species, and age group that the*
16 *antibiotic will be used for.*

17 (5) *Any other information that the department deems*
18 *necessary.*

19 (c) *The department may increase fees on holders of licenses*
20 *subject to this section. The increase in fees shall not exceed the*
21 *department's costs of collecting, collating, and disseminating*
22 *information pursuant to this section.*

23 SEC. 3. *Section 15051 of the Food and Agricultural Code is*
24 *amended to read:*

25 15051. (a) Each person shall obtain a license from the
26 secretary for each location where commercial feed is
27 manufactured, distributed, sold, or stored for later sale. Persons
28 who do not have a permanent place of business, but who otherwise
29 manufacture, sell, or store feed shall also obtain a license from the
30 secretary.

31 (b) This section also shall apply to a person whenever the
32 person's name and address appears on the label of commercial feed
33 as guarantor.

34 (c) The following persons are exempt from this section:

35 (1) A person that makes only retail sales of commercial feed
36 which bear the tag or other approved indication that the
37 commercial feed is from a licensed manufacturer or guarantor who
38 has assumed full tax responsibility for the tonnage tax due under
39 this chapter.

1 (2) A person who manufactures commercial feed exclusively
2 for feeding to his or her own animals.

3 (d) *Notwithstanding subdivisions (a), (b), and (c), a holder of*
4 *a license under this section shall report to the department, on a*
5 *form prescribed by the department, all sales of feed that contain*
6 *antibiotics. The form shall include, but is not limited to, all of the*
7 *following:*

8 (1) *The NADA code and identity of the antibiotic, including its*
9 *generic and trade name.*

10 (2) *The quantity of the antibiotic-containing feed sold.*

11 (3) *The percentage of antibiotic per volume of feed.*

12 (4) *The claimed use, targeted species, and age group that the*
13 *antibiotic will be used for.*

14 (5) *Any other information that the department deems*
15 *necessary.*

16 (e) *The department may increase fees on holders of licenses*
17 *subject to this section. The increase in fees shall not exceed the*
18 *department's costs of collecting, collating, and disseminating*
19 *information pursuant to this section. The moneys from the fees*
20 *shall be available upon appropriation by the Legislature.*

21 SEC. 4. No reimbursement is required by this act pursuant to
22 Section 6 of Article XIII B of the California Constitution because
23 the only costs that may be incurred by a local agency or school
24 district will be incurred because this act creates a new crime or
25 infraction, eliminates a crime or infraction, or changes the penalty
26 for a crime or infraction, within the meaning of Section 17556 of
27 the Government Code, or changes the definition of a crime within
28 the meaning of Section 6 of Article XIII B of the California
29 Constitution.